September 8, 2001
931 Central Avenue
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Blood Products Advisory Committee
Food and Drug Administration
Center for Biologics, Education & Research
1401 Rockville Pike
Rockville, Maryland 20852

Dear Committee Members,

On September 30, 1999 the FDA released proposed tissue donation regulations, which, if enacted, would almost eliminate the possibility of gay men from accessing fertility medical care in the United States. I am writing because you have been asked to advise on the suitability of gay semen donors(men who have sex with men a.k.a. MSM's). I want you to be aware that your decisions will not only have impact on the suitability of MSM's as anonymous semen donors but will impact the larger questions of gay men's access to fertility medical care.

I am also asking you to look to the State of California for guidance. California has both a law as well as proposed regulations which satisfy both the safety and ethical issues while preserving gay men's reproductive rights. The proposed FDA regulations would override California's proposed regulations as well as California's law. The FDA proposal was formulated by government employees who know little of the sperm banking industry. The California proposal was written by the State Health Department in collaboration with blood, sperm and tissue bankers in open public sessions. The traditional FDA "Notice and Comment" period is after the fact when positions have already been taken. The California process included tissue banking professionals before the first sentence was written.

I am aware that several months ago you discussed the possibility of gay men being blood donors and the present policy was sustained by a one vote margin. However, I want to emphasis that semen is very different than blood. I will elaborate on three areas which make semen donation very different from blood donation:

1. the types of donors,
2. safety, and
3. it's ethical and legal implications.

There are three types of semen donors: directed, identity release and anonymous.

Directed Donors

According to California law[1] (California Heath and Safety Code Division 2 - Chapter 4.2 Section 1644.5) a directed donor is "a sperm donor known to the recipient." In California, women are allowed to use fresh, unfrozen, unquarantined sperm as long as the donor has been tested and "found nonreactive by laboratory tests for evidence of infection with HIV, agents of viral hepatitis (HBV and HCV), human T lymphotrophic virus-1 (HTLV-1), and

[1] This is law passed by the Legislature and signed by the Governor, not regulation written by the State Health Dept.

syphilis."

Fresh insemination with directed donors would be prohibited by the FDA proposal by mandating directed donors have their semen frozen and quarantine for six months and the donor retested before his semen is released. This goes way beyond tissue banking. Any physician, nurse practitioner or licensed midwife can do fresh insemination with directed donors. At present, most inseminations are done by licensed health professionals who properly screen donors and counsel recipients on their risks. California's law mandates such screening and counseling. If the FDA forbids fresh insemination with directed donors they will only stop licensed health professionals from assisting this process. Additionally, this will encourage the increasing number of home self-inseminations without the appropriate testing and counseling a licensed professional can provide. In short, the FDA will be increase the risk of disease transmission.

If the FDA's proposal becomes regulation, there are three reasons why women wishing to conceive with a directed donor will continue to do fresh insemination outside of the medical care system. First, pregnancy rates are significantly higher with fresh sperm than with frozen sperm. I have submitted other papers for you inspection which sites the medical literature supporting this fact. Since many women seeking fresh insemination with directed donors are older with decreasing fertility, this is an very important factor. Second, older women are reluctant to wait out a six month quarantine because fertility declines very rapidly after 40. Finally, only about one in six men have sperm that survives the freezing process well enough for their sperm to be used for vaginal insemination.[2] Some in the FDA claim that over 90% of all men have sperm that survives the freezing process well enough for their sperm to be used in vaginal insemination. However, none of the medical literature even vaguely supports this contention and, despite our repeated requests for documentation of this claim over a three year period, those people have failed to produce one such study. Indeed, in a recent conversation with Dr. Ruth Solomon she admitted she has not seen a single study that supports this contention. Regardless, of sperm cryosurvival, the FDA has never disputed a higher pregnancy rate with fresh insemination.

Given the fact that only a minority of men have sperm that survives the freezing process well enough for their sperm to be used for vaginal insemination, the FDA's proposal would eliminate most men a woman might choose to conceive with. This would also mean that gay men with low sperm counts would be barred from seeking medical assistance or must use in vitro fertilization (IVF). IVF is rarely covered by insurance and costs $10,000 to $15,000 per attempt.

Identity Release Donor, Anonymous Donors and Safety

More and more women are requesting gay sperm donors and they want to eventually know the donor's identity. Identity release donation uses only frozen donors with the same screening and quarantine as anonymous donors. Denying women the opportunity to have identity release gay donors will increase unsupervised home fresh inseminations which are done with minimal, if any, testing, and no counseling and quarantine period.

It is particularly important to restate at this juncture that semen is not like blood. Unlike

[2] The World Health Organization defines minimal fertility as ≥20 million motile cells per cc of seminal fluid.

blood which cannot be frozen, some semen can successfully be frozen, held in quarantine for 6 months and the donor retested before his semen is released for insemination. Therefore, the most crucial question is: "What percentage of people, who are infected with HIV, do not show up positive on the antibody test 6 months after infection?" On May 7, 1996 I asked experts in HIV disease at the Center for Disease Control this question. In two separate telephone conversations I spoke with Tom Spira, M.D., Assistant Chief for Medical Science for the Centers for Disease Control in Atlanta, Georgia and with Charles Schable, Chief of the AIDS Diagnostic Laboratory at the Centers for Disease Control in Atlanta, Georgia.

Tom Spira: "I want to make it clear I am speaking for myself and my own opinion and not the CDC."

Leland Traiman: "Do you think it is appropriate to exclude 'men who have had sex with other men in the last 5 years' as potential semen donors?"

Tom Spira: "The rate of false negatives is quite low. I would not, categorically, want to exclude them since we have appropriate testing. If you do so, I believe, you gain a false sense of security. I would suggest testing all donors for p24 or PCR at 6 months to be sure. Of course, with the proviso that no testing is 100% accurate."

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Leland Traiman: "What is the percent of false negatives to the HIV antibody test?"

Charles Schable: "I have been doing this (working with AIDS) since 1983 and there are only 6 cases of false negatives, 4 men and 2 women. People who are negative to the antibody test but are antigen positive, who really are infected, have other things wrong with them."

Leland Traiman: "Where is this documented?"

Charles Schable: "Well, we've tried to look for true false negatives and there are so few cases that there are only a few articles that have popped up from time to time documenting those cases."

Leland Traiman: "Given that the window period is 3 months..."

Charles Schable: "The average window period is 25 days. That is the average, some people take a longer. But the most recent test that labs are using now is 25 days."

Leland Traiman: "How many people would take longer than 6 months to seroconvert?"

Charles Schable: "By 6 months everyone would have seroconverted unless they are otherwise immuno-compromised and cannot mount an antibody

response. They are sick."

Leland Traiman: "Semen donors are otherwise generally healthy people, so if one were doing a through examination of them it would be obvious?"

Charles Schable: "Yes."

Leland Traiman: "The reason why I am calling is because the State of California is considering new sperm banking regulations. They want to use the CDC guidelines for tissue donation which bar any man who has had sex with a man in the last 5 years.[3] Unlike blood and other tissue products, semen donation can be frozen and quarantined for 6 months. Then the donor is retested for HIV. Given what you said about the window period, is it justified to apply this criterion to semen donation?"

Charles Schable: "If one is freezing the sperm and retesting the donor after 6 months the only reason to apply that criterion to semen donors is homophobia."

On December 11, 1997 the Blood Products Advisory Committee discussed the topic of allowing MSM's to be blood donor. The FDA's Dr. Andrew Dayton described "a two-phase testing scenario" for blood banks that "would basically have the effect of dropping the prevalence problems to zero." All sperm bank already follow a similar "two-phase testing scenario."[4]

A Member of this Committee, Dr. Jeanne Linden, Director of New York's Blood and Tissue Resources Program, suggested a pretest for MSM blood donors at a Committee meeting earlier this year. Dr. Linden's suggestion along with Dr. Dayton's "two-phase testing scenario" could be combined into a screening and testing program creating a three-phase testing scenario. Indeed, my own facility already uses such a three phase testing scenario. We require a donor to have had a negative HIV test prior to screening, we perform second HIV test at their physical exam and a third HIV test six months after their last donation. All of their samples are in quarantine until their final negative test.[5]

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[3] California's Tissue Banking Proposal: "The USPHS Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs are to assist the Medical Director in formulating appropriate guidelines for their facility. Notwithstanding the USPHS Guidelines, the Medical Director shall take into account current medical information in formulating their facility's guidelines." The "notwithstanding" clause means that tissue banks may ignore the MSM ban.

[4] "One compromise which is suggested -- now, we are not proposing this as policy, but we are throwing this on the table as the kind of issue that may want to be discussed -- is basically to have a two-phase testing scenario whereby if we reduce the exclusion time to five years or one year, whatever, the people who are newly admitted would first go through an HIV test before they could donate, but they wouldn't give a unit, and then at a certain time period afterwards, they could come back if the first test was negative and donate as would anyone else, and then be tested again of course.

"This would basically have the effect of dropping the prevalence problem to zero. I suspect that this would be a very complicated thing for collecting centers to do, and I am sure we will get some comment on that." Transcript of the Blood Products Advisory Committee, December 11, 1997, Topic I: Donor Deferral Policy Regarding Men Who Have Had Sex With Another Man, Even One Time, Since 1977

[5] Their final test includes rescreening for HIV 1 & 2, hepatitis B & C, HTLV 1 and syphilis

With a pretest, test, quarantine and final testing protocol there is no safety reason for categorically excluding gay men as anonymous donors or identity release donors. In other words, it is not necessary, for safety reasons, to identify a sub-group of gay men that is at low risk for infection because the protocol is sufficient screening. None-the-less, we go one step further and identify a sub-group of gay men that is low risk for HIV infection by taking a detailed sexual history.[6] Of course, identifying low risk gay donors is crucial for directed donation. I have stopped more directed donor inseminations than I have assisted because of the information I have gotten from the screening tool described in our study. Most of the recipients in these inseminations said that if my services had not been available they would have done home insemination with their directed donors.

Some in the FDA have sited preliminary data from a study of young gay men, as yet unpublished, to refute the fact that sub-groups of gay men at low risk for HIV exists. The exact phrase used was, "There is no sub-group of gay men with a lower incidence of HIV." This is such an extreme, unsupportable statement which would be laughable if were not for the fact that those who claim to be objective scientists are putting it forward. (Indeed, the CDC's Charles Schable did laugh at the absurdity of this statement.) This statement contradicts all other studies which show lifestyle and risk reduction behaviors work. If one is to believe such an unfortunate statement then the only sensible course would be to stop wasting money on risk reduction education. Almost two decades of HIV policy in this country proves otherwise. Additionally, the study in question is looking at young men, most of whom were recruited from sexual pick-up venues. I fail to see how men in their early 20's found in such venues, where drugs and alcohol are present, represents men in their 30's and 40's in long term mutually monogamous relationships. Clearly, those trying to extrapolate this data from this limited group to all gay men are either very poor scientists or have something other than science in mind.

Given that there is no health risk using semen if one observes the 6 month quarantine, this issue should be one of informed consent, not one of exclusion. The donor's sexual orientation, as well as many other specific pieces of information about the donor, should be included in a recipients informed consent agreement.

Legal and Ethical Issues

There is a fundamental difference between blood and semen donation. After blood donation, both the donor and recipient go about their separate lives. However, semen donation creates a new human being who is inextricably tied to both the donor and the recipient. Most sperm donation children are, in effect, half-adopted children. The donor has relinquished his child for adoption. From the perspective of a child who wishes to answer the fundamental questions of "Who am I?" and "Where do I come from?" it makes little difference if such relinquishment was before conception or after birth. Many children of single women and lesbian couples start asking as young as three years of age who their fathers are. Because their children want the answers to these questions, women are turning to directed donation and identity release donation. Women, mostly lesbians but certainly not all, specifically want gay donors whose identity will be know to them. Others want a specific donor and, for fertility reasons, wish to have fresh inseminations. Your Committee can recognize these realities and help the FDA fashion 21st century safety

[6] **Identifying a sub-set of Gay men who are at low risk for HIV infection** by Leland Traiman, RN/FNP; Fred Strauss, MD; Stewart Blandón, MD

regulations as California has done or you can approve the FDA's present proposal which fits the science and the social realities of the early 1980's.

In June, 2000 Supreme Court Justice Sandra Day O'Connor said, "The demographic changes of the past century make it difficult to speak of an average American family." This most definitely applies to identity release donors. I run a program where the identity is released when the child is three months old. Many of these identity release donors develop significant relationships with their biological children and play an uncle-type role in these children's lives. Indeed, this is the way that some gay men have chosen to bring children into their lives. This is the way they have chosen to procreate. Although one may argue that there is no inherent right to be an anonymous semen donor the same argument falls flat when one actually sees the relationship that children and identity release donors develop. Identity release donation gives concrete meaning to Justice O'Connor's words.

Given the 6 month quarantine and retesting, no valid scientific reason has been offered to exclude gay semen donors; therefore, excluding gay men from donating would be unconstitutional. In Romer v. Evans[7] decided May 20, 1996 Justice Kennedy, writing for the majority of the United States Supreme Court, wrote: "The Fourteenth Amendment's promise that no person shall be denied equal protection of the law must co-exist with practical necessity." He continues, "We have attempted to reconcile the principle with the reality by stating that, if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the legislative classification so long as it bears a rational relation to some legitimate end." As there is no "rational relation to some legitimate end," i.e. the public is not protected by the FDA's proposed regulations; and such a regulation would "burden a fundamental right," i.e. the right to have children; and would target gay men, therefore, to exclude gay donors would fly in the face of the Supreme Court's decision.

Finally, I would be remiss if I did not say how frightened many lesbians and gay men are of the FDA's proposal. With regards to directed donation, many feel the FDA is invading a private family decision best left to the participants and their physician. All feel guidance from the FDA would be appropriate. But they feel the FDA's proposed regulations are inappropriately intrusive. Given the freeze and quarantine for anonymous and identity release, donation all feel it to be bigotry not public safety.

Unfortunately, the United States Public Health Service has a long history of this kind of unscientific bigotry. James H. Jones's book "Bad Blood: the Tuskegee Syphilis Experiment" documents the USPHS's history of using pseudoscience to perpetuate bigotry against African-Americans. The blanket reference to all gay semen donors as "donors who are at risk for HIV-infection" is all too similar to the the phrase "a notoriously syphilis-soaked race" that the physicians who began the Tuskegee Study used in reference to African-Americans. In the last chapter of his book Professor Jones warns the gay community that the USPHS may try to use HIV against us as it used syphilis against African-Americans. A decade after it's publication the FDA has devised regulations which would make Professor Jones's prediction a reality. I urge you to be guided by the facts and protect the public health from both HIV and from bigotry masquerading as science. I urge you to follow

[7] A voter passed Colorado state constitutional amendment which prohibited laws protecting lesbians and gay men from discrimination was overturned by the United States Supreme Court on a six to three decision.

California's lead and not bar gay men from being either directed, identity release or anonymous sperm donors.

Mr. Jones's book contains the following plea and admonishment:

> "As a symbol of racism and medical malfeasance, the Tuskegee Study may never move the nation to action, but it can change the way Americans view illness. Hidden within the anger and anguish of those who decry the experiment is a plea for government authorities and medical officials to hear the fears of people whose faith has been damaged, to deal with their concerns directly, and to acknowledge the link between public health and community trust. Government authorities and medical officials must strive to cleanse medicine of social infections by eliminating any type of racial or moral stereo-typing of people or their illnesses."

Respectfully,

Leland Traiman, RN/FNP